Regulatory Guide 10.8

Instructions for the Preparation of Medical Radioactive Materials License Application

Medical Radioactive Materials License Application
Application Index

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Form RHF-2	Training and Experience Authorized User or Radiation Safety Officer – Preceptor Statement

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Instructions for the Preparation of Application for Medical Licenses

Contents of an Application

The following paragraphs explain the information requested on form RHF-1M:

Item 1a. Enter the name, mailing address, E-Mail address, Fax and telephone number of the applicant institution. It is particularly important that the mailing address be sufficiently complete so all correspondence to the licensee will reach persons actually responsible for the radiation safety program.

Item 1b. List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual locations of use should be listed, whether or not they are the same as the mailing address in Item 1a; e.g., a P.O. Box may be more suitable for Item 1a in some cases, but a P.O. Box does not adequately describe the location of use. Item 1b must be an in-state address.

Item 2. Enter the name, telephone number (including area code), and Email address of the individual to be contacted.

Item 3. Indicate whether this is an application for a new license, an amendment, or a renewal.

Item 4. List the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include the physicians who supervise other physicians in training and/or who will direct technologists or other medical personnel in the use of radioactive material for human or nonhuman use. Non-physicians may be authorized to use radioactive material for nonhuman use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

A. Approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radionuclide sources.

B. Prescription of the radiopharmaceutical or source of radiation, and the amount or dose to be administered.

C. Determination of the route of administration.

D. Interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Items A-D may be delegated to physicians who are in training under the supervision* of authorized physician-users.

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* Supervision means that the physician-user has adequately instructed the physician(s) in training in the specific human use and has ascertained that they are receiving training in the safe use of these materials in humans. It also means that the physician-user periodically reviews and documents the work of those supervised and assures himself that proper medical records are made of each use. It does not mean that the physician-user is necessarily present for each radiopharmaceutical administration.

Properly trained technicians, technologists, or other medical personnel under an authorized user's direction may be delegated the following activities:

A. The preparation and quality control testing of radiopharmaceuticals and sources of radiation.

B. The measurement of radiopharmaceutical doses prior to administration.

C. The use of appropriate instrumentation for the collection of data to be used by the physician.

D. The administration of radiopharmaceuticals and radiation from radionuclide sources to patients, as permitted under applicable federal, state, and local laws.

Item 5. State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the Radiation Safety Officer is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities, and the amount of time to be devoted to the radiation safety program. **Also submit the name of the person responsible for the radiation program on a day-to-day basi**s.

Item 6a. For routine human use, the applicant may check the group numbers of Schedule A in WAC 246-235-120 for which the license is requested. Groups I, II, and III consist of the more commonly used diagnostic procedures that involve radio-pharmaceuticals; Groups IV and V consist of routine therapeutic procedures that involve radiopharmaceuticals; and Group VI consists of sealed sources used primarily for therapeutic procedures.

For Groups I, II, IV, V, and VI, possession limits are not listed on the license.

For Group III, the possession limit will be two curies (74 gigabecquerels) of each radioactive material listed unless a larger limit is requested in the application. The possession limit for each radionuclide should be sufficient to include material held as radioactive waste.

Item 6b. For routine human use not listed in Groups I through VI and for nonhuman use, list each radionuclide to be used, the chemical and physical form, and the maximum quantity (in millicuries or becquerels).

List the manufacturer's name, model number, and activity (in millicuries or becquerels) for all sealed sources. Sealed sources (excluding Radium 226) up to 3 mCi (or up to 5.5 mCi for Cobalt 57) used for calibration and reference standards are authorized under WAC 246-235-080(3)(c) and need not be listed.

Describe the intended use for each radionuclide and form listed in Item 6b. A specific authorization must be obtained from the department to perform studies involving the use of radioactive material in animals. The information required is specified in Item 23.

If the radioactive material is for human use and has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that procurement, preparation, and use of the material will be in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. If the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit, and use, and submit a copy of the IND acceptance letter from the FDA. If a study is to be conducted under a protocol approved by an FDA-approved Radioactive Drug Research Committee, submit a copy of the FDA letter granting approval; state the radionuclide, chemical form, possession limit, and use; and submit a copy of the protocol.

Item 7. **Radiation Safety Committee**. In accordance with WAC 246-235-080(1)(a), an institution applying for a radioactive materials license for human use is required to establish a radiation safety committee. This committee evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes. Membership of the committee must include at a minimum:

A. Physicians specializing in nuclear medicine, internal medicine, and either hematology or pathology, at least one of whom will use or directly supervise the use of radioactive materials for diagnosis and/or treatment of humans.

B. A person with special competence in radiation safety.

C. A representative of the institution's management.

D. A representative of the nursing staff.

Submit the following information:

A. The responsibility and duties of the committee.

B. The meeting frequency of the committee (at least quarterly).

C. The name and specialty of each member of the committee.

Attachment A to the medical application contains an example of typical responsibilities and duties for a radiation safety committee. Indicate, by checking the appropriate box in Item 7, that the responsibilities, duties, and meeting frequency will be as described in Attachment A, and sign, date, and include the attachment with the application. **Attachment A, the application, cover page and Attachment P (ALARA), should each be signed by the representative of the institution's administration.**

Item 8. **Radiation Safety Office**r. Include a description of the duties and responsibilities of the Radiation Safety Officer (RSO). **Attachment B** contains typical duties for an RSO. If these duties/ responsibilities are adopted, indicate by checking the appropriate box in Item 8 of form RHF-1M and sign, date, and include Attachment B, (or submit an equivalent description).

Item 9. **Training and Experience**

A. **Authorized User(s)**. If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license name and number (if issued by the Department) or a full, complete, and current copy of the license (if issued by another Agreement State or the NRC).

If the physician has not been previously authorized to use the radioactive material being requested, state where he is licensed to practice medicine, and submit a complete description of this training and experience. Remember to submit a copy of the current and valid license to practice medicine in Washington State. Use Form RHF-2 to describe the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix A of these instructions.

B. **Radiation Safety Office**r. If the RSO is not one of the physicians named in Item 4, submit a complete description of his or her training and experience. Items 1, 4, and 5 of Form RHF-2, Attachment A, may be used to describe the RSO's training and experience. Where a consultant is employed to assist the RSO, the institution will still be responsible for the proper performance of the radiation safety program as required by the license, and the institution's RSO will be expected to review the consultant's work and sign the required reports and records.

Item 10. Instrumentation. Instruments generally required in a typical nuclear medicine operation are:

A. Survey instruments

(1) A low-level survey meter, with a thin window of 1-7 mg/cm 2, to perform contamination surveys. This instrument will usually be calibrated for Beta efficiency; and when used for contamination surveys, will yield results in counts per minute (CPM).

(2) A high-level survey meter, such as an ionization-type, capable of reading up to at least 1 Roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99/Tc-99m generators and therapeutic quantities of radioactive material such as I-131 or IR-192.

B. Dose calibrators and other instruments to assay radiopharmaceuticals.

C. Instruments used for diagnostic procedures in nuclear medicine (e.g., gamma camera, thyroid probe, well counter, scintillation counter for in-vitro studies).

D. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Attachment C to the medical application contains a form which may be used to describe the instruments. Complete this form by listing the instruments to be used. If this form is not used, attach equivalent information. Check the appropriate box in Item 10 of Form RHF-1M.

Item 11. Calibration of Instruments

A. **Survey Instruments**. An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are inadequate to determine the proper functioning and response of an instrument.

Daily constancy checks of survey instruments should be made before and after each use and should be supplemented at least every 12 months with a battery check and two-point calibration (at about 1/3 and 2/3 of full scale) on each scale of the instrument to be used for radiation protection surveys.* Survey instruments should also be calibrated after repair or maintenance that may affect the calibration of the instrument.

A dose rate survey instrument may be considered properly calibrated at one point when the exposure rate measured by the instrument differs from the true exposure rate by less than 10 percent.

Beta efficiency calibrations are appropriate for contamination instruments and probes. If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures. Include in the description:

(1). The manufacturer's name and model number of the source(s) to be used. The source should be of sufficient strength to give at least a 2/3 scale reading on the highest scale to be calibrated when the source is 20 cm from the effective center of the detector.

(2). The nuclide and either (a) activity (in millicuries or becquerels) of radioactive material contained in the source or (b) exposure rates at fixed distances from the source as certified by measurements involving direct comparisons with sources or dosimeters calibrated at the National Institute of Standards and Technology (NIST).

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* Scales up to 1 R/hr should be calibrated, but in order to keep personnel exposures ALARA, high-range scales above 1 R/hr need not be calibrated when they will not be needed in a particular institution. Scales above 1 R/hr that are not calibrated should be checked for operation when possible. The results should be noted on the instrument. The user should be alerted to scales not calibrated or checked.
Section 2 of Attachment D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to supply the information required in Item 11 of this application form. Indicate, by checking the appropriate box in Item 11 of **Form RHF-1M**, if the procedure in Attachment D for calibrating dose calibrators will be followed, submit equivalent procedures.

(3) The accuracy** of the source(s).

(4) The step-by procedures, including associated radiation safety procedures. For each instrument, these procedures should include a two-point calibration (at about 1/3 and 2/3 of full scale) on each scale used for radiation protection surveys.*

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify name, address, and the license number. Contact the firm or consultant that will provide the calibration to determine whether information concerning calibration services and procedures has been filed with the department. If this information has not been filed, submit it with your application, including details of the information the outside firm will supply you about the results of the calibration.

Indicate whether the outside firm or consultant is NVLAP-certified. If not a Washington licensee, include a copy of the certification. Section 1 of Attachment D to the medical application contains an acceptable procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 11 of the application form. A sample "Certificate of Instrument Calibration" is also provided for use by a consultant in reporting calibration results. Indicate, by checking the appropriate boxes in Item 11 of Form RHF-1M if the procedures de-scribed in Attachment D will be followed; sign, date, and include Attachment D (or submit equivalent procedures).

B. **Dose Calibrato**r. All radiopharmaceuticals must be assayed for activity to an accuracy of ± 10 percent of the true value prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation, and periodically thereafter, dose calibrators must be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

Submit a description of your calibration procedures. These should include, as a minimum:

(1) The manufacturer's name and model number of any sealed sources to be used (unless authorized by WAC 246-235-080(3)(c)).

(2) The nuclide and activity (in millicuries or becquerels) of radioactive materials in the standards.

(3) The accuracy and traceability of the standard.

(4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

(1) The instrument and operating parameters.

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* Scales up to 1 R/hr should be calibrated, but in order to keep personnel exposures ALARA, high-range scales above 1 R/hr need not be calibrated when they will not be needed in a particular institution. Scales above 1 R/hr that are not calibrated should be checked for operation when possible. The results should be noted on the instrument. The user should be alerted to scales not calibrated or checked.
Section 2 of Attachment D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to supply the information required in Item 11 of this application form. Indicate, by checking the appropriate box in Item 11 of **Form RHF-1**M, if the procedure in Attachment D for calibrating dose calibrators will be followed, submit equivalent procedures.

** The maximum deviation of the nominal value of the source from the true value. The manufacturer normally provides this information.

(2) The assay method.

(3) The method of calibration.

(4) The frequency of calibration.

(5) The standards to be used for calibration (radionuclide, activity, accuracy).

Section 2 of Attachment D contains a description of an acceptable procedure for calibrating dose calibrators and a form that may be used to supply the information required in Item 11 of this application. Indicate, by checking the appropriate box in Item 11 of **Form RHF-1M**, if the procedure in Attachment D for calibrating dose calibrators will be followed, (or submit equivalent procedures).

C. **Instruments Used for Diagnostic Purpose**s. Calibration, quality control, and maintenance of instrumentation used for diagnostic procedures should be performed routinely in accordance with the manufacturer's recommendations. On the space provided in Attachment D or on a separate sheet include a description of calibration and quality control program, including tests and checks performed, the frequency with which they are performed, and records that are maintained.

Item 12 **Facilities and Equipmen**t.* Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, and measurement of radioactive material.

Submit a detailed diagram of the facility; including the type, dimensions, position, and thickness of shielding that will be used for:

A. Use and storage of Tc-99m generators;

B. Storage of radiopharmaceuticals (refrigerated and non-refrigerated);

C. Storage of radioactive waste, including decay-in-storage prior to disposal as non-radioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste.) If this area is located outside your department, describe how the material will be secured, and designate on area diagram. Confirm that this area will be surveyed at least weekly.

D. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block).

Identify areas adjacent to use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in immediate unrestricted areas do not exceed the limits specified in WAC 246-221-060 (see Figure 1).

Shielding requirements for the walls, floor, and ceiling should be evaluated for each nuclear medicine room based on total workload, the energy of radiation, and the presence of patients with activity in the room. Adequate distances must be allowed between technologists and patients containing radioactive material.

*See also U.S. Nuclear Regulatory Commission Regulatory Guide 8.18 and NUREG-0267 for checklists of facilities, equipment, and procedures to consider in designing hospitals for medical uses of radioactive material.

If gas or aerosol is to be used, submit a gas or aerosol facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where gas or aerosol will be used or stored. This information is necessary in order to determine that the vents are properly located and that use and storage areas are under negative pressure. (See Figure N-1 of Attachment N for an example of the type of diagram to be submitted).

For other facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale, or indicate dimensions.

Building drawing goes here.

EXAMPLE of an Acceptable Type of Layout Diagram for a Facility Description Including Shielding Provisions. (Indicate Shielding in Millimeters or Inches)

Item 13. Personnel Training Program. Radiation workers (e.g., technologists) must receive instruction as specified in WAC 246-222-030. Note that many of these items pertain to circumstances at a particular institution; therefore, it may not be assumed that this instruction has been adequately covered by prior occupational training, board certification, etc. Outline and submit the program for providing the necessary instruction.

Ancillary personnel (e.g., clerical, nursing, housekeeping, security personnel) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials. Include the form of training (e.g., formal course work, lectures), frequency of training, duration of training, and subject matter.

Verify that personnel will be properly instructed:

A. Before assuming duties with, or in the vicinity of, radioactive materials.

B. During annual refresher training.

C. Whenever there is a significant change in duties, regulations, or the terms or conditions of the license.

Instruction required by WAC 246-222 should include:

A. All terms of the license pertinent to radiation safety.

B. Areas where radioactive material is used or stored.

C. Potential hazards associated with radioactive material.

D. Radiological safety procedures appropriate to their respective duties.

E. Pertinent regulations and license conditions.

F. Obligation to report unsafe conditions to the RSO.

G. Appropriate response to emergencies or unsafe conditions.

H. Right to be informed of their radiation exposure and bioassay results.

I. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by WAC 246-222.

Attachment E provides a minimum training program. If this program is adopted, check the appropriate box in Item 13 of Form RHF-1M and sign, date, and include Attachment E (or submit an equivalent training program).

Item 14. Procedures for Ordering and Receiving Radioactive Material. Describe procedures for ordering radioactive materials, for receiving materials during off-duty hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures should ensure that possession limits are not exceeded, that radioactive materials ordered for human use are adequately verified upon receipt and checked before use, that radioactive materials are secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in WAC 246-221-060(1).

Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours should be issued **written instructions** for procedures to be followed for (a) receiving, examining, and securing packages, and (b) notifying specific personnel (including names and telephone numbers of persons to be contacted) if the package is found or suspected to be leaking, and the immediate steps to be taken to prevent spread of contamination.

Attachment F to the application contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures or, if the procedures in Attachment F are to be followed, sign, date, and include Attachment F (or attach equivalent procedures).

Item 15. Procedures for Safely Opening Packages Containing Radioactive Materials. Although WAC 246-221-160 exempts certain packages from immediate monitoring, WAC 246-221-160(4) requires that each licensee establish procedures for safely opening all packages containing licensed material.

Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for compliance with WAC 246-221-160. Monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for (a) surveying packages, (b) wearing gloves while opening packages, (c) checking packing material for contamination after opening, and (d) verifying package contents.

Attachment G contains a description of an acceptable procedure for safely opening packages. Indicate, by checking the appropriate box in Item 15 of **Form RHF-1M** that the procedure in Attachment G will be followed, sign, date, and include Attachment G, (or attach equivalent procedures).

Item 16. General Rules for the Safe Use of Radioactive Material. Describe the general instructions to be followed by physicians, radiopharmacists, and technologists while working with radioactive materials. The instructions should:

A. Outline control procedures for obtaining permission to use radioactive material at the institution.

B. Explain what laboratory apparel to wear and what equipment to use; e.g., wear laboratory coats and disposable gloves, and use trays.

C. Prescribe limitations and conditions for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or glove boxes.

D. Specify the shielding or remote handling equipment to be used when hard beta- and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals from reagent kits should always be done behind shielding and within appropriate hoods or enclosures. Syringe shields should be used for the routine preparation and administration of patient doses, except on the rare occasions where difficulties in properly administering the dose to the patient would warrant expedited use of lighter syringes. Even in these cases, syringes with the best possible finger protection or remote delivery of the dose (e.g., through use of a butterfly valve) should be used.

E. Give instructions for preparation and assay of patient doses, including instructions to check each therapy dose against the ordering physician's **written** request.

F. Give instructions concerning movement of material between rooms, in halls, or in corridors, as applicable.

G. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive materials are used. Describe the shielding used for areas where large amounts of byproduct material are stored.

H. Specify personnel monitoring devices to be used, where to obtain them, procedures for properly turning in personnel monitoring devices for processing at appropriate intervals, and instructions for recording exposure results. Also describe where personnel monitoring devices and control dosimeters will be stored to ensure accuracy in monitoring employee occupational exposures and to avoid inadvertent exposure of the devices when they are not being worn.

I. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived). Properly shielded waste receptacles should be employed for used syringes and other radioactive wastes.

J. Describe contamination control procedures, including (1) prohibitions against smoking, eating, chewing, drinking, or applying cosmetics in restricted areas, (2) prohibition against storing food, beverages, and personal effects with radioactive materials, and (3) instructions for individuals who prepare and administer doses of radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For smaller programs, **Attachment H** to the sample application contains an acceptable set of laboratory rules for the safe use of radioactive material. Indicate by checking the appropriate box in Item 16 of RHF-1M. If Attachment H rules will be followed, sign, date, and include Attachment H, (or attach equivalent procedures).

Item 17. Emergency Procedures. Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should: (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, evacuation of the area, containment of the spill); (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency; and (c) instruct personnel on appropriate methods for re-entering, decontaminating, and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in **Attachment I**. Indicate, by checking the appropriate box in Item 17 of **RHF-1**M, that you will follow the emergency procedures, sign, date, and include Attachment I, (or submit a copy of equivalent procedures).

Item 18. Area Survey Procedures. Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining adequate records of surveys.*****

If the application is to cover multiple users and areas of use, the individual user should perform surveys of his own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in **Attachment J**. Indicate, by checking the appropriate box in Item 18 of Form RHF-1M that you will follow those survey procedures, sign, date, and include Attachment J, (or submit equivalent procedures).

Item 19. Waste Disposal. Describe specific methods used for disposal of waste material. A licensee may dispose of waste by:

* Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions" provides further information on acceptable survey procedures.

A. Careful segregation of non-radioactive waste from radioactive waste, decay of radioactive waste in storage, monitoring, and release to normal trash. Waste may be held for decay until radiation levels, as measured in a low background area with a low-level survey meter with all shielding removed, have reached background levels. Then, after radiation labels have been removed or obliterated and appropriate survey and background results recorded, the waste may be disposed in normal trash.

B. Release into a sanitary sewer in conformance with WAC 246-221-190. Describe the methods for controlling the sewerage disposals of radioactive wastes in order to ensure that disposals do not exceed the limits specified in WAC 246-221-190.

C. Release into the air in conformance with WAC 246-221-070 and WAC 246-247.

D. Other methods specifically approved by the department in accordance with WAC 246-221-180.

E. Transfer to a person or firm properly licensed to receive such waste, e.g., commercial waste disposal firms (see WAC 246-221-170). Submit the name and the NRC or Agreement State license number of the commercial firm(s) selected.

The Department is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from non-radioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials into the sanitary sewer (paragraphs A and B above).

Attachment K contains a form which may be used to supply the information requested in Item 19 of the application form. Indicate, by checking the appropriate box in Item 19 of Form RHF-1M, that you will dispose of wastes as specified on the form; sign, date, and include Attachment K, (or attach equivalent information).

Item 20. Therapeutic Use of Radiopharmaceuticals. Describe special precautions* for patients treated with radioactive material listed in Groups IV and V, Schedule A, WAC 246-235-120. Although Group IV procedures are often performed on an outpatient basis, appropriate procedures should be established because hospitalization is sometimes required.

A. Describe radiation safety procedures associated with the care of therapy patients, including:

(1) Procedures for assigning patients to rooms. Private rooms should be designated for I-131 therapy patients or any other patients who may constitute an internal or external exposure hazard for roommates.

(2) Procedures for contamination control in the patient's room (e.g., protective covering for areas of likely contact, use of disposable dishes and utensils, and procedures for posting and controlling radiation areas or potentially contaminated areas (see NUREG-0267)).

(3) Procedures for surveys of:

(a) Areas, equipment, and personnel involved in administration of radiopharmaceuticals;

(b) The patient's room on a daily basis;

(c) Unrestricted areas (i.e., areas adjacent to the patient's room); and

*See Regulatory Guide 8.23 and NUREG-0267.

(d) Linens and other items removed from the patient's room; and

(e) The patient's room before it is reassigned to another patient.

(4) Records of surveys to be recorded on the patient's chart and in radiation safety office records.

(5) Instructions to nursing staff (**see Attachment L**).

(6) Personnel monitoring procedures for medical and nursing staff.

(7) Procedures for disposal of wastes, including:

(a) Patient excreta

(b) Surgical dressings

(c) Other disposable items

(8) Procedures to be followed in case of emergency surgery or death (see NRCP Report Nos. 37 and 48).

(9) Procedures for release of patients, including:

(a) Criteria for release of patients. (Reg Guide 8.39.)

(b) Instructions to patients and families (see NCRP Report Nos. 37 and 48).

B. Describe radiation safety procedures involved with all other aspects of therapy procedures, including:

(1) Criteria for determining when it is appropriate to use protective facilities, equipment, or supplies (e.g., hoods, shielding blocks, tongs, disposable gloves) and procedures for their use. Personnel should always wear gloves and work within fume hoods or special enclosures whenever opening vials containing therapeutic quantities of volatile radiopharmaceuticals such as I-131. These hoods should have adequate airflow, and operating procedures should be designed to prevent contamination of personnel and surrounding areas.

(2) Criteria and procedures for bioassay of personnel: Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of I-131 for therapeutic doses. Bioassays should also be considered for personnel (e.g., radiation safety, nursing) who are involved in other aspects of therapy procedures. Guidance on situations requiring bioassay for I-131 and appropriate action levels may be found in Regulatory Guide 8.20, "Bioassay Program Criteria for I-125 and I-131."

(3) Surveys to limit the spread of contamination and procedures for decontamination. Surveys (e.g., measurement of I-131 in air, measurement of I-131 in the thyroid glands of laboratory personnel, contamination surveys of personnel, equipment, and facilities) should also be performed to determine compliance with WAC 246-221-040 and WAC 246-221-070.

Submit detailed responses to Items 20A and 20B. (In lieu of submitting a detailed response to Item 20a, state that you will follow the procedures in Attachment L. Sign, date, and return Attachment L.)

Item 21. Therapeutic Use of Sealed Sources. Describe special procedures for patients treated with; Intravascular brachytherapy devices; High Dose Rate Remote Afterloader; and radioactive materials listed in Group VI in Schedule A, WAC 246-235-120. These procedures* should include descriptions of:

A. The areas where the sealed sources will be stored, including: (1) placement and thickness of shielding; (2) proximity of the storage area to unrestricted areas; and (3) any calculations or measurement data used to check the adequacy of the shielding and other facility protection specifications. Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour and less than 100 millirems in any 7 consecutive days (see WAC 246-221-060).

B. Special precautions to be used while using or handling IVB, HDR, or other sealed sources.

C. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.

D. The equipment and shielding available for transporting sources from storage to the place of use.

E. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic (at least quarterly) inventory, and the method for determining that all sources are accounted for and returned to storage immediately following explant and cleaning.

F. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument immediately following the conclusion of treatment and before the patient is discharged. This survey should include a documented source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

G. Special instructions for nursing personnel who care for patients treated with sealed sources. (**Attachment M** to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

Submit detailed responses to Item Nos. 21A through 21F. In response to Item 21G, indicate by checking the appropriate box in Item 21, that the procedures described in Attachment M will be followed; sign, date, and include Attachment M, (or submit equivalent procedures).

Item 22. Procedures and precautions for Use of Radioactive Gases and Aerosols. The use of radioactive gases (e.g., Xe-133 gas or gas in saline) and aerosols requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas or aerosol in restricted and unrestricted areas. The department requires that each applicant make such determinations for his own unique situation and submit sufficient evidence to the department to adequately support the request.

Attachment N to the medical application contains instructions for submitting an application to use Xe-133 or aerosol. The information requested in Attachment N must be submitted.

Item 23. Procedures and Precautions for Use of Radioactive Material in Animals. Describe procedures to be followed if radionuclides will be used in animals, including

(A) A description of the animal housing facilities,

* Guidance on facilities, equipment, and procedures is available in NUREG-0267.

(B) A copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses,

(C) Instructions for cleaning and decontaminating animal cages, and

(D) Procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material. Instructions to animal caretakers should reflect the types of studies done at the institution.

Item 24. Procedures and Precautions of Radioactive Materials Specified in Item 6b. Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 6b, e.g., air sampling, other special surveys, bioassay, leak testing of sealed sources, including radiation safety precautions.

Bioassay may be required when individuals work with millicurie quantities of H-3, I-125, or I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassay may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Show in the application that the need for bioassay has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material. Guidance on bioassay programs for I-125 and I-131 is provided in Regulatory Guide 8.20, and for tritium in Regulatory Guide 8.32 (formerly, 8.99). Guidance for bioassay programs for other radionuclides is available from the Division of Radiation Protection.

Item 25. Personnel Monitoring, Bioassay and Sealed Source Leak Test Programs.

25a. Personnel Monitoring Devices. Provide the name of the organization furnishing film, thermoluminescent dosimeter (TLD) or Luxel service. Specify the frequency with which the devices are changed and evaluated, and give a description of the type; e.g., whole-body, wrist, or finger. Where wrist devices are worn to monitor extremity exposures, and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist data in lieu of using finger monitors, and provide any backup data used to perform or verify these estimates. Wrist or ring devices should be worn toward the palm side of the hand for measuring hand exposures. Where feasible, rings should be worn on the index finger facing toward the palm side of the hand. When pocket ionization chambers (pocket dosimeters) are to be used for personnel monitoring, give the manufacturer's name, model number, range of scale readings, calibration and check procedures, frequency of calibration, and frequency of readings and recording exposures. Use **Attachment O** to provide personnel monitoring information.

25b Bioassay Program. If I-125 and/or I-131 is handled or processed, include bioassay program information. Appendix B (Regulatory Guide 8.20) to this guide provides criteria for the development and implementation of a bioassay program. The program as described in Appendix B may be used to satisfy the bioassay program requirement. If the Appendix B program is not compatible with your operation, submit a description of an equivalent program. Attachment O should be used to provide bioassay program support information.

25c Sealed Source Leak Test Program. Pursuant to WAC 246-221-080, each radioactive sealed source possessed under the provisions of a specific license, other than H-3, greater than 100 microcuries for beta and gamma emitters and greater than 10 microcuries for alpha emitters, must be tested for leakage and/or contamination prior to initial use and at six-month intervals or at time intervals specified by the license. Use Attachment O to provide sealed source leak test program information.

Item 26. **(For Private Practice Applicants Only**).

26a. State the name and address of the hospital that has agreed to admit patients containing radioactive material.

26b. Submit a copy of the letter of authorization, signed by the administrator, from the hospital that has agreed to admit patients containing radioactive material.

26c. If patients treated with therapeutic quantities under this license are admitted to the hospital,

(1) describe the radiation detection instruments available at the hospital and

(2) submit a copy of radiation safety procedures to be followed.

Item 27. **"ALARA" - As Low As Reasonably Achievabl**e. WAC 246-220-007 states that "persons engaged in activities under licenses issued by The Washington State Department of Health pursuant to the Atomic Energy Act of 1954, as amended, shall, in addition to complying with the requirements set forth in Chapter 246-221 WAC, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable (ALARA). The term 'as low as is reasonably achievable' means as low as is readily achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and in relation to the utilization of nuclear energy, ionizing radiation, and radioactive materials in the public interest."

Applications for new licenses, renewal requests, and requests for significant license amendments (i.e., to broaden programs; to increase possession limits) should be accompanied by a description of the applicant's/licensee's ALARA program. Applicants/licensees may adopt the model program described in **Attachment P** of the application or may develop and submit for department review an equivalent alternate program. If the model program in Attachment P is adopted, check the appropriate box in Item 27 on Form RHF-1M. Attachment P should be dated and must be signed by a representative of Administration and must be attached to the request for licensing action.

Item 28. Please complete and attach your facility's Quality Management Program. If you administer no therapeutic radioactive material and no amounts of Iodine - 131 as Sodium Iodide greater than 30 microcuries, please so state, and check the "N/A" box. Remember also to submit complete QMP's for IVB, teletherapy, HDR, and/or brachytherapy seed programs.

Item 29. Please be certain to enter the fee category code for the license and submit the requisite fee. If the application is for a **new** license, remember to also submit the one-time fee for new license application review.

Item 30. Indicate whether the liability indemnification certificate is completed and attached, or not submitted.

Item 31. Provide the signature of an individual authorized by management to represent an applicant institution, or the signature of an individual physician, in the case of private practice or a non-institutional clinic, with the date of signature.

Amendments

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or Radiation Safety Officer, or radioactive material to be used. The amendment must be approved and issued in writing by the Department **prior** to the proposed change(s).

Applications for license amendments may be filed either on an application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

Amendment applications must be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator). An original of the application for amendment should be prepared, and the original must be submitted, as is the case for new or renewal applications.

Prepare an original and one copy of the application. Retain the copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplements to it. Mail the original to: Washington State Department of Health, Division of Radiation Protection, Box 47827, Olympia, Washington 98504, Attention: Radioactive Materials Section.

Instructions
Appendix A

Acceptable Training and Experience for Medical Uses of Radioactive Material

1. **General Criteria**

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation therefrom, to human beings) must be carried out by, or under the supervision of, a physician. A physician means an individual licensed by the state to dispense drugs in the practice of medicine.

WAC 246-235-080 provides that the Department will approve a license application by an institution for medical use of radioactive material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in: (a) basic radionuclide handling techniques; and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Similar criteria are established in WAC 246-235-080(2) for the approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the department has found acceptable for physicians who use radiopharmaceuticals.

2. **Training for Routine Diagnostic Procedures (Groups I-III)**

To qualify as adequately trained to use, or directly supervise the use of, byproduct material listed in Groups I, II, and/or III in WAC 246-235-120, a physician should have: (200 hours) *

A. **Training** in basic radionuclide handling techniques applicable to the use of unsealed sources. This training should consist of lectures, laboratory sessions, discussion groups, and/or supervised experience in a nuclear medicine laboratory (i.e., on-the-job training in a formalized training program) in the following areas:

(1) Radiation physics and instrumentation	(100 hours)
(2) Radiation protection	(30 hours)
(3) Mathematics pertaining to the use and measurement of radioactivity	(20 hours)
(4) Radiation biology	(20 hours)

* The hours are in terms of class, laboratory, or clinical experience rather than semester hours.

(5) Radiopharmaceutical chemistry (30 hours)

(The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

B. **Experience** with the types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). For authorization for Group III (generators and reagent kits), this experience should include **personal participation in at least five procedures to elute Tc-99**m, including testing of eluate, and **at least five procedures to prepare radiopharmaceuticals from Group III reagent kits.**

C. **Supervised clinical training** in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

(1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.

(3) Follow-up of patients when required.

(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

Note A: The requirements specified in Sections 2A, B, and C may be satisfied concurrently in a six-month training program IF all three areas are integrated into the program.

Note B: For each physician named in Item 4 of Form RHF-1M, complete Training and Experience and Preceptor Statement parts of Form RHF-2. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job (OJT). **OJT must have been obtained in a formalized training program**. Be sure that individual hours of training can be readily traced to the institution where the training was received. Each hour of training should be listed under only one subject category (i.e., the most applicable subject category).

Alternatives

Certification by (1) the American Board of Nuclear Medicine, or (2) the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology or Nuclear Medicine will be accepted as evidence that a physician has adequate training and experience to use Groups I, II, and III.

3. Training for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radionuclide handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the department.

4. Training for Therapy Procedures Involving Radiopharmaceuticals (Groups IV & V)

To qualify as adequately trained to use or directly supervise the use of radioactive material defined in Groups IV and/or V in WAC 246-235-120, a physician should have:

A. **Training in basic radionuclide handling techniques** applicable to the use of unsealed sources for therapy procedures, including: (80 hours)

(1) Radiation physics and instrumentation (25 hours)

(2) Radiation protection (25 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity.(10 hours)

(4) Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those specified in Section 2 above).

B. Minimum **clinical training in specific therapy procedure**s: **For Group IV**

(1) I-131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function, and active participation in the treatment of **ten patient**s.

(2) Soluble P-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of **three patients** with any combination of these three conditions.

(3) Colloidal P-32 for intracavitary treatment:

Active participation in the treatment of **three patient**s.

For Group V

(1) I-131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function, personal participation in the treatment of **ten patients with hyperthyroidism and/or cardiac dysfunctio**n, and active participation in the treatment of three patients with thyroid carcinoma.

(2) Colloidal Au-198 for intracavitary treatment:

Active participation in the treatment of **three patient**s.

5. Training for Therapy Procedures Involving Sealed Sources (Group VI)

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI in WAC 246-235-120, a physician should have:

A. **Training in basic radionuclide handling techniques** applicable to the use of sealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas: (200 hours)

(1) Radiation physics and instrumentation (110 hours)

(2) Radiation protection (40 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (25 hours)

(4) Radiation biology (25 hours)

(The hours listed next to each of the four subjects above are suggested values and need not be interpreted as specific requirements.)

B. **Experience** with the types and quantities of radioactive material for which the application is made, or equivalent (500 hours).

C. **Clinical training** in Group VI procedures:

Active practice in therapeutic radiology with a minimum of three years experience, of which at least one year should have been spent in a formal training program accredited by the Residency review Committee of Radiology and the Liaison Committee on Graduate Medical Education.

As evidence of the foregoing training and experience, the applicant should complete Form RHF-2. The preceptor statement portion of RHF-2 should be completed and signed by each preceptor-physician under whom the applicant-physician gained experience or training. Submission of letters of evaluation from each preceptor-physician on behalf of the applicant-physician should be included with the application. These letters of evaluation should describe the scope and extent of the applicant-physician's training and experience and should include an appraisal of the applicant-physician's competency to use Group VI sources independently for therapy procedures.

Special training and documentation is required for IVB and HDR use.

Note:

Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology; certification as a British "Fellow of the Faculty of Radiology" (FCR) or "Fellow of the Royal College of Radiology" (FRCR); or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the information requested in Sections 5.A through C above. Physicians certified by the FCR or FRCR must also submit evidence of specialization in radiotherapy. Evidence of previous approval by the state, the NRC or another Agreement State may also be submitted in lieu of the information requested above. In this case, the applicant should specify the name and number of the state license or submit a copy of the Agreement State or the NRC license on which the applicant-physician was specifically listed as an authorized user.

6. **Training for Physicians Wishing to Use Sr-90 Ophthalmic Eye Applicators Only**

To qualify as adequately trained to use or supervise the use of a Sr-90 eye applicator only, a physician should submit evidence of:

A. Certification by the American Board of Radiology in Radiology or Therapeutic Radiology, or

B. (1) Active practice in therapeutic radiology or ophthalmology, and

(2) Training in basic radionuclide handling techniques, including: (24 hours)

(a) Radiation physics and instrumentation (6 hours)

(b) Radiation protection (6 hours)

(c) Mathematics pertaining to the use and measurement of radioactivity (4 hours)

(d) Radiation biology (8 hours)

(This information may be submitted on the training and experience part of Form RHF-2. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.)

(3) Evidence of active participation in the treatment of **five patient**s, to be submitted on the Preceptor Statement portion of Form RHF-2.

"Active Participation" must include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and follow-up and study of patient case histories.